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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,625	03/09/2001	Elizabeth A. Wang	5160C-CON	2656

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EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/804,625	<b>Applicant(s)</b> WANG ET AL.	
	<b>Examiner</b> David S. Romeo	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24, 26, 30, 33, 35, 36, 38, 39, 41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24, 26, 30, 35, 38 and 41 is/are allowed.
- 6) ☒ Claim(s) 33, 36, 39 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed 11/16/2005 has been entered. Claims 24, 26, 30, 33, 35, 36, 38, 39, 41 and 42 are pending and being examined.

#### **Maintained Formal Matters, Objections, and/or Rejections:**

##### ***Claim Rejections - 35 USC § 102***

Claims 33, 36, 39 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Wozney (Science. 1988 Dec 16;242(4885):1528-34).

The claims are directed to or encompass a polynucleotide that hybridizes under “stringent hybridization conditions.” The specification has been amended to insert stringent hybridization conditions that are asserted to have been incorporated by reference. See the amendment to the specification at page 7, line 35. However, the inserted material is new matter, as discussed below. Therefore, the amendment changes the meaning scope or content of the claims. Hence, the effective filing of the claims is the filing date of the present application.

Applicants argue that the claims are adequately described in U. S. Application No. 07/179,100 and Applicants are entitled to the April 8, 1988 filing date. Applicants argue that the hybridization conditions are well known in the art. Applicants’ arguments have been fully considered but they are not persuasive. Maniatis indicates that washing conditions vary depending upon the particular hybrid under study (page 388, paragraph 11, see *Note*). Maniatis also indicates that hybridizations may also be carried out in buffers containing formamide (page 389, see **Notes**). At best it might have been obvious to the skilled artisan that it would be desirable to employ Maniatis to derive some set of hybridization conditions and buffers to practice the disclosed methods in some of the contexts contemplated in the specification.

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However, the written description does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. One shows that one is "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious.

**New Formal Matters, Objections, and/or Rejections:**

***Specification***

The amendment filed 11/16/2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment to the specification at page 7, line 35. It is acknowledged that the specification refers to "Maniatis et al. ... pages 387 to 389" but the only mention of stringency in the indicated pages of Maniatis is in reference to the wash conditions (page 388, paragraph 11, see *Note*). Yet Applicants are attempting a wholesale importation of Maniatis' method of hybridization of Southern filters. It is not clear that Applicants intended to incorporate by reference Maniatis' entire method of hybridization of Southern filters. Also, the hybridization conditions inserted into the specification differ from those in Maniatis with respect to the components of the prehybridization and hybridization buffers and the time and temperature of the washes. Furthermore, mere reference to another publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

Claims 33, 36, 39 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to or encompass a polynucleotide that hybridizes under “stringent hybridization conditions.” The specification has been amended to insert stringent hybridization conditions that are asserted to have been incorporated by reference. See the amendment to the specification at page 7, line 35. However, the inserted material is new matter, as discussed above, and changes the meaning, scope or content of the claims. Hence, the claims encompass new matter.

Claims 33, 36, 39 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to or encompass a polynucleotide that hybridizes under “stringent hybridization conditions.” However, Maniatis indicates that washing conditions vary depending upon the particular hybrid under study (page 388, paragraph 11, see *Note*). Maniatis also indicates that hybridizations may also be carried out in buffers containing formamide (page 389, see *Notes*). The metes and bounds of the hybridization conditions are not clearly set forth.

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***Double Patenting***

Claims 33, 36, 39 and 42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 11 of U.S. Patent No. 5,166,058. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are generic to and fully encompass the claims of the patent.

***Conclusion***

Claims 24, 26, 30, 35, 38 and 41 are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

DSR  
FEBRUARY 2, 2006